

C L A I M S

1. A medical device (10) with a proximal end (22) and a distal end (23), an elastomeric bulb (21) at the proximal end for storing fluid under pressure, a fluid acceptor (20) at the distal end and a lumen (12) connecting the bulb and the acceptor for flow of fluid from the bulb to the acceptor when the device is used, and including a control device (25) at the proximal end of the lumen to prevent said flow until said flow is desired
characterised in that
said control device (25) comprises a plug (26) which blocks the lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid communication along the lumen from the elastomeric bulb (21) to the fluid acceptor (20) to fully fill the acceptor.
2. Device as claimed in claim 1 wherein the bulb (21) is coated with a substance to inhibit the passage of the fluid through the wall thickness of the bulb.
3. Device as claimed in claim 2 wherein the coating is on the outside of the bulb wall thickness.
4. Device as claimed in claim 2 wherein the coating is on the inside surface of the bulb wall.
5. Device as claimed in claim 1 wherein the plug (26) carries a fluid-tight skirt membrane which extends proximally from the proximal end face of the plug.
6. Device as claimed in any one of the preceding claims, wherein the acceptor is a balloon (20).

7. Device ~~as~~ claimed in any one of the preceding claims wherein the medical device is a catheter (10).
8. Device as claimed in claim 7 wherein the catheter is a drainage catheter.
9. A medical device which is a drainage catheter (10) having a proximal end (22) and a distal end (23) and first and second lumens extending therebetween, the first lumen serving as a drainage lumen and having a fluid inflow port at its distal end and a fluid drain coupling at its proximal end, the second lumen serving to convey inflating fluid from a fluid supply element (21) at its proximal end to a fluid acceptor balloon (20) at its distal end, with the fluid supply element (21) and the fluid drain coupling arranged side by side at the proximal end of the lumen
characterised by
a sleeve which extends around both the fluid drain coupling and the fluid supply element.
10. A device as claimed in claim 9, wherein the fluid supply element is a elastomeric bulb to be inflated with said fluid, and the sleeve is of a material which is more impervious to said fluid than is the elastomeric material of said bulb (21) thereby to have the effect of slowing the rate of loss of fluid radially outwardly from the bulb (21) through the wall thickness of the bulb.
11. A device as claimed in claim 10 wherein the control device (25) comprises a plug which blocks the second lumen at its proximal end and includes a parting line, which enables the plug to be parted into two separate parts, by manual manipulation from outside the lumen, such parting having the effect of opening up fluid

communication along the lumen from the elastomeric bulb (21) to the fluid acceptor (20) to fully fill the acceptor.

- 5/21
12. Device as claimed in any one of the preceding claims, wherein the acceptor (20) is made of elastomer.
13. Device as claimed in any one of the preceding claims and made of latex rubber.
14. Device as claimed in any one of the preceding claims wherein the fluid is a liquid, and the fluid supply element (21) contains said fluid.
15. Device as claimed in claim 14 wherein the fluid is water.
- 5/22
16. Device as claimed in any one of claims 1 to 8, 11, or any one of claims 12 to 15 as dependent on claim 11, wherein the plug comprises a co-axial stem (27) and annular part (26), which meet at said parting line.
17. Device as claimed in claim 16 wherein the annular part comprises an annulus (26) of material with a proximal end face (30) and a distal end face (28) and a bore (29) extending between the two end faces.
- 5/23
18. Device as claimed in claim 16 or 17, wherein said stem (27) extends proximal of the annular part, coaxially therewith and has an outside diameter substantially less than that of said annular part (26).
19. Device as claimed in claim 18 wherein the stem is friction fitted within the bore (29) of the annular part.

20. Device as claimed in claim 18 wherein the stem (27) is integral with the annular part and joined to it by a circle of weakness (31).
21. Device as claimed in claim 20 wherein the annular part and stem are together formed as only one piece of molded polymer material.
22. Device as claimed in any one of claims 16 to 21, wherein the annular part comprises a tapering portion displaying a small end and a large end, the small end being remote from the stem.
23. Device as claimed in any one of claims 16 to 22, wherein the annular part comprises a cylindrical portion.
24. Device as claimed in claim 23, as dependent on claim 22, wherein the cylindrical portion lies between the tapering portion and the stem, in the axial direction of the plug.
25. Device as claimed in claim 24 wherein the diameter of the cylindrical portion is greater than that of the large end of the tapering portion.
26. Device as claimed in claim 25, including a step between the large end of the tapering portion and the cylindrical portion.
27. Device as claimed in any one of claims 16 to 26, wherein the axial length of the annular part is greater than its largest diameter.
28. Device as claimed in claim 24, or any one of claims 25 to 27 as dependent on claim 24, wherein the length of the cylindrical portion is smaller than its radius.

29. Device as claimed in claim 22, or any one of claims 23 to 28 as dependent on claim 22, in which the tapering portion comprises a frusto-conical or substantially frusto-conical portion which has a small end which is larger than the small end of the tapering portion.
30. Device as claimed in claim 22, or any one of claims 23 to 29 as dependent on claim 22, in which the tapering portion comprises a frusto-conical or substantially frusto-conical portion which has a small end which constitutes the small end of the tapering portion.
31. Device as claimed in claim 30, as dependent on claim 29, wherein the tapering portion comprises first and second frusto-conical or substantially frusto-conical portions, of different cone angle, such that the diameter of the tapering portion varies along the axis at a greater rate near the small end of the tapering portion than at the large end of the tapering portion.
32. Device as claimed in any one of claims 16 to 31 in which the stem is cylindrical and has a diameter not more than half of the largest diameter of the annular part of the plug.
33. Device as claimed in any one of the preceding claims wherein the fluid supply element (21) has an open proximal end (22) closed by a filler valve (24).
34. Device as claimed in any one of the preceding claims, and which is a urinary drainage catheter.
35. Device as claimed in claim 34 wherein the catheter is a Foley catheter.
36. Plug for use as a flow control device in a medical device as claimed in any one of the preceding claims.

37. Method of positioning a plug within a lumen of a medical device, the method comprising the steps of:
- i. providing the plug with an annular portion and a stem, co-axial with the annular portion and having a diameter substantially less than that of the annular portion, the annular portion sealing with the lumen wall;
 - ii. presenting an open end of the lumen, for receipt of said plug;
 - iii. engaging the stem of the plug with an injector rod;
 - iv. advancing the injector rod into the lumen open end and along the lumen to the desired position within the lumen.
38. Apparatus for positing a stemmed plug within a lumen of a medical device, the apparatus comprising:
- i. expansion fingers to engage and widen the open end of said lumen; and
 - ii. an injector rod to engage the stem of the plug and advance the plug into the open end and along the lumen to a desired position within the lumen.
39. Apparatus as claimed in claim 9, or any one of claims 10 to 34 as dependent on claim 9, wherein the sleeve is of shrink-wrap material.
40. Apparatus as claimed in any one of claims 1 to 8 wherein the elastomeric bulb is sleeved in shrink-wrap material.
41. Apparatus as claimed in claim 39 or 40 wherein the permeability of the sleeve material to diffusion of water therethrough is less than that of latex rubber.
42. Apparatus as claimed in claim 39 or 40 wherein the shrink-wrap material is polystyrene.

43. Apparatus as claimed in any one of claims 39 to 42 wherein the shrink-wrap sleeve incorporates a tear strip.